



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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November 18, 2002

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-2-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas J. Whennen, Sr., CEO
Triple A Services, Inc.
2637 S. Throop Street
Chicago, IL 60608

Dear Mr. Whennen:

The Food and Drug Administration (FDA) conducted inspections of your firm on April 22, 23, 24 and 26, 2002, and on May 24, 2002, and found serious violations of Sections 402(a)(4), 403(i)(2) and 403(k) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act, and the applicable regulations, in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), Food Labeling, and Part 110 (21 CFR 110), Good Manufacturing Practice for Manufacturing, Packing or Holding Human Food, through links on FDA's home page at www.fda.gov.

Our determinations, in regard to the deviations we found during the current inspections, are as follows:

LABELING:

Sandwich and specialty products that include your TWIN EGG ROLL, CHEESE DOG, BEEF & CHEESE (sandwich), and CHORIZO & EGG TORTA are misbranded under Section 403(i)(2) of the Act, and under 21 CFR 101.4(b)(2), in that the labels of these products fail to declare constituent ingredients, some of which are known allergens. The TWIN EGG ROLL is also misbranded under Sections 403(i)(2) and 403(k) of the Act for failure to list certified color additives.

- The TWIN EGG ROLL label does not list the sub-ingredients for the egg rolls and sauce. These include:
 - Shrimp and wheat flour, which are known allergens.

- The colors, FD&C Yellow #5 and FD&C Yellow #6. The presence of these undeclared colors misbrands the product under Sections 403(i)(2) and 403(k) of the Act. Certified color additives must be individually declared in the ingredient statement by their common or usual name, e.g. FD&C Yellow #5 and FD&C Yellow #6, as required by 21 CFR 102.22(k)(1).
- › The CHEESE DOG label does not list sub-ingredients, some of which are constituents of the bun, including wheat flour, wheat gluten, soya flour, whey and casein and/or caseinate. Each of these undeclared ingredients is a known allergen. Additionally, during the inspection we observed that the cheese ingredient used in the product is "imitation cheddar cheese topping"; however, the ingredient statement on the Cheese Dog label simply lists the cheese ingredient as cheddar cheese. The ingredient statement must be revised to declare the cheese ingredient by its proper common or usual name, which is "imitation cheddar cheese".
- › The BEEF & CHEESE (sandwich) label does not list sub-ingredients including wheat flour, hydrolyzed wheat gluten, soy protein, milk and cream, each of which is a known allergen. The sub-ingredients of the bun, a French bread roll from [REDACTED] that your firm uses for this product, were unknown by your firm at the time of our inspection.
- › The CHORIZO & EGG TORTA label does not list the sub-ingredient wheat, which is a known allergen.

Undeclared ingredients that are known allergens are of particular concern to the agency. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustacea, tree nuts, wheat, peanuts, and soybeans.

INSANITARY CONDITIONS

The inspection disclosed insanitary conditions that cause products manufactured in your facility to be adulterated under Section 402(a)(4) of the Act. Under that provision, food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth. The insanitary conditions observed in your facility during the inspection included the following:

□ BIRD/INSECT ACTIVITY & FECAL MATERIAL

- Numerous birds (pigeons, robins, etc.) were observed in flight and defecating in the truck bay area, where finished product, including open containers of baked goods, are loaded onto out-going catering trucks. Raw materials were also observed being unloaded in this area, including produce containers with exposed contents, while numerous birds were flying and walking around.
- Bird feces were observed caked on the wall, rafters and overhead pipes in the truck bay area noted above, where finished product is loaded onto trucks, and where raw materials were observed being unloaded.
- Ants were observed in the dry bakery goods storage area, within approximately five inches of a pallet of flour.
- Feces were observed in one corner of the truck bay area, approximately five feet from a product loading point for catering vans. A sample of this fecal material was collected during our inspection and was confirmed by our laboratory as mammalian feces.

□ INSANITARY EMPLOYEE PRACTICES

- A worker was observed dropping a roll of paper towels onto the production area floor, sheets from which she then used to wipe both a processing knife and the production table, during production of sandwiches containing Polish sausage and green peppers.
- A worker was observed handling/discarding garbage from off the floor, and then handling sandwich product (Polish sausage and green peppers) on the conveyor belt, without first washing his hands or changing gloves.
- Open bags of [REDACTED] and [REDACTED] which were not currently in production use, were observed in and around the dry bakery goods storage area.

□ STRUCTURAL DEFECTS

- Water from the cooling unit in the south cooler was observed dripping on unidentified containers of product (labeled "Pierre") in the south cooler, near the production room.
- Gaps were observed in several truck bay overhead doors, two truck-bay pedestrian doors, and the lunch room door leading to waste receptacles outside. Gaps were also observed between the roof and the building in the truck bay/receiving area; there were holes in the roof in this same area. Truck bay overhead doors and the kitchen door leading to outside waste receptacles were left open during our inspection. Gaps, holes, and open doors in a food facility can allow pests to enter and contaminate food manufactured or held there.
- Yard waste (tree limbs) was piled outside next to the north side of the building, providing potential harborage for rodents, in an area approximately 25 feet from an open overhead door leading to the truck bay area.

□ INSANITARY OPERATIONS

- A water pipe, located in the product holding area adjacent to (and opening into) the production room, and situated five inches from an open container of washed, ready-to-use lettuce, had mold and condensate on it. An observation concerning mold on this same pipe was previously reported to you in the FDA Form 483 issued at the end of our inspection of April 10 and 12, 2001. In addition, environmental swabs taken from the exterior of this pipe during the April 2002 inspection tested positive for Listeria monocytogenes. L. mono was also identified in tuna salad collected in our February 2001 inspection and in two environmental swabs from the April 2001 inspection. One positive swab was taken from the same pipe during the April 2001 inspection.

At the close of the inspection, your firm's President, Mr. Scott Whennen, was issued a Form FDA 483, which is a list of our investigator's observations during our inspection. (A copy of the FDA 483 is enclosed.) Before the end of our inspection, we confirmed various corrections your firm made to deficiencies in your operations/facility. These included cleaning the mold from the water pipe in the product holding area, as well as corrections to other items listed on the FDA 483.

While we acknowledge these corrective actions, your response to the labeling deficiencies and insanitary conditions described above should include a specific, comprehensive approach to monitor and prevent product misbranding and adulteration in the future.

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The above-listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence to each requirement of the Act and its regulations, including being vigilant that products received, manufactured, stored and distributed meet all requirements. We request that you take prompt action to correct all violations.

Please provide this office, within 15 days of receipt of this letter, a detailed response stating the actions you plan to take, or have taken, to correct and prevent the objectionable conditions we have cited. (It is not necessary to report the corrections we confirmed before the end of our inspection, unless you have additional relevant information.) Provide the specific time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Your reply should be directed to James Karpus, Compliance Officer, at the address listed in the letterhead.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director



cc w/enclosure: Mr. Scott Whennen, President
Triple A Services
2637 S.Throop Street
Chicago, IL 60608

cc w/enclosure: Mr. David A. Frisco, General Manager
Triple A Services
2637 S.Throop Street
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cc w/enclosure: Mr. Frank H. Shields, Night Supervisor
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